

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-0695 and the expiration date is 2/28/2021. The time required to complete this information collection is estimated to average 30 minutes per response, including the time for reviewing instructions, and completing and reviewing the collection of information.

ATTACHMENT C2 LABEL COMPREHENSION STUDY TASK 3: STRUCTURED INTERVIEW GUIDE – ADULT ALL COMERS (Group 4)

GROUP NUMBER: _____

PARTICIPANT ID: _____

INTERVIEWER INITIALS: _____

INTERVIEW DATE/TIME: _____

Group 4 Screening Questions (Note: for all questions except literacy level, the interviewer enters data from the participant grid provided by the recruitment firm) The interviewer's tablet will have entries for each of these screening questions with answer categories that the interviewer will select from- e.g. for "Ethnicity—Hispanic" the interviewer will select "yes" or "no". For literacy level, this data will be entered not from the participant grid, but from the REALM test that will be administered immediately after administration of the consent form.

Group 4 Screening Questions (enter data)

- Age
- Education
- Ethnicity—Hispanic: Yes/No
- Race
- Gender
- Household income
- Confidence filling out medical forms
- Help reading instructions, pamphlets, or other written information
- Literacy Level: NL/LL

INFORMED CONSENT

INTERVIEWER TO BRING PARTICIPANT TO ROOM:

VERIFY THAT THE PARTICIPANT STILL AGREES TO BE AUDIO RECORDED. [IF THEY OBJECT, DISMISS AND DO NOT PROVIDE REIMBURSEMENT.]

PARTICIPANTS MUST SIGN CONSENT FORM AT THE TIME OF THEIR INTERVIEW IN FRONT OF THE INTERVIEWER.

Before we get started I'm going to give you an informed consent form that describes the study and what you'll be asked to do in more detail. I'm going to give you two copies—one for you to sign for us and one for you to take home. Please take a few minutes to read the form. Once you are finished reading, we will talk through any questions you might have. Please do not sign anything yet.

HAND THE PARTICIPANT THE CONSENT FORM AND ASK THEM TO LET YOU KNOW WHEN THEY ARE DONE READING IT.

ONCE THE PARTICIPANT IS FINISHED, REVIEW EACH SECTION OF THE CONSENT FORM WITH THE PARTICIPANT AND EMPHASIZE THAT THEY SHOULD NOT REVEAL PII DURING THE INTERVIEW.

THEN ASK THE FOLLOWING:

A. Do you have any questions about the consent form that you just read?

DISCUSS QUESTIONS	YES	1
CONTINUE	NO	2

B. Do you wish to participate in the study?

CONTINUE	YES	1
THANK AND TERMINATE	NO	2

ONCE ALL QUESTIONS ARE ADDRESSED AND PARTICIPANT AGREES TO PARTICIPATE, ASK PARTICIPANT TO SIGN THEIR NAME, AND DATE THE LAST PAGE. THE INTERVIEWER IS TO...

- 1. SIGN AND DATE THE LAST PAGE AS A WITNESS.**
- 2. GIVE THE PARTICIPANT A COPY OF THE CONSENT FORM FOR THEIR RECORDS.**

REALM TEST

ADMINISTER REALM TEST AND PLACE SCORE IN THE BLANK BELOW.

Hello, my name is [NAME] and I'm going to be conducting today's interview.

First, I would like to show you a word list of medical-related terms. These words are sometimes found on packages of medicines.

Please look at this list of words, beginning here **[POINT TO FIRST WORD]**. Say all of the words you know. If you come to a word you don't know, you can sound it out or just skip it and go on.

ENTER REALM SCORE: **RECORD LITERACY SUBGROUP ON PAGE 1**

INTRODUCTION

Once again, thank you for agreeing to participate in our study today. Your opinions are very important and we appreciate your time.

Today I will be showing you a label for a medicine that is currently available only by prescription, but may become available over-the-counter without a prescription. I would like

for you to read the entire label and then I will ask you to answer some questions about what you have just read. We want to make sure that the label is clear and understandable even if this is something that you may or may not personally use.

Please read the label and take as much time as you need. When you are through, we will begin with the questions. During my questions, you will be able to refer back to the label as often as you like. I'm going to step out of the room now - please come to the door and let me know when you are finished.

HAND THE PARTICIPANT THE LABEL (INTERVIEWER TO ALTERNATE LABELS FOR EACH INTERVIEW).

LEAVE INTERVIEWING AREA AND WAIT FOR THE PARTICIPANT TO LET YOU KNOW WHEN THEY HAVE FINISHED WITH THE LABEL.

RETURN TO THE INTERVIEWING AREA.

IF PARTICIPANT ASKS ANY QUESTIONS, RESPOND WITH: To make sure that each person is interviewed the same, I cannot give you any information other than what is on my script. Please keep in mind that I am testing the label and I am not testing you.

Part 1: **COGNITIVE WALKTHROUGH**

Now, I would like for you to answer some questions about what you have just read. My questions will be about what you have read on the label, not your personal experience or thoughts on what you would do. We are testing the words on the label.

I want to stress that I am testing the label and not testing you.

1. "Imagine you were in a situation where you had to use this product on a friend. Talk out loud and explain to me what you would do based on the label."

INTERVIEWER: DOCUMENT RESPONSES, SEQUENCE, AREAS OF STATED/APPARENT CONFUSION ON OBSERVER'S CHECKLIST

TASKS		ORDER	ADDITIONAL COMMENTS
Steps 1-5	(Radio Buttons to select)	(Drop-down #s)	Additional Participant Comments
Cognitive Walkthrough	Mentioned	Order	
Step 1: CHECK			
<i>Check</i>			
<i>Yell "Wake up"</i>			
<i>Shake the person gently</i>			
<i>Try to wake the person up</i>			
<i>If person is not awake, go to step 2</i>			
<i>Other (Specify):</i>			
Step 2: GIVE 1 st dose			
<i>Give 1st dose</i>			
<i>Give the medicine</i>			
<i>Other (Specify):</i>			
Step 3: CALL			
<i>Call 911 immediately after giving the 1st dose</i>			
<i>Call 911</i>			
<i>Other (Specify):</i>			
Step 4: WATCH & GIVE			
<i>Wait 2-3 minutes after 1st dose</i>			
<i>If the person wakes up, go to Step 5</i>			
<i>If person does not wake up – continue to give doses every 2-3 minutes</i>			
<i>It is safe to keep giving doses</i>			
<i>Other (Specify):</i>			
Step 5: STAY			
<i>Stay until ambulance arrives</i>			
<i>Stay with the person</i>			
<i>Give another dose if person gets sleepy again</i>			
<i>Other (Specify):</i>			
Comments			
<p>Note: Calling 911 must be mentioned within steps 1-3 to be considered "correct" or within steps 1-5 to be "acceptable".</p>			

Part 2: LABEL COMPREHENSION

Once again, I would like for you to answer some questions about what you read on the label. My questions will be about what you have read on the label, not your personal experience or thoughts on what you would do. We are testing the words on the label.

I want to stress that I am testing the label and not testing you.

Here is a booklet of the questions I am going to ask so you can follow along as I read them aloud. Please do not skip ahead, but wait for me to tell you when to go to the next page. Keep in mind this is not a memory test, so you can refer back to the label as often as you would like during the interview.

HAND PARTICIPANT THE BOOKLET OF SHOWCARDS.

FOR ALL QUESTIONS: INTERVIEWER SELECT THE RESPONSE THAT CORRESPONDS TO THE PARTICIPANT'S ANSWER TO EACH QUESTION UNLESS OTHERWISE SPECIFIED.

Please turn to Card A. **READ CARD ALOUD TO THE PARTICIPANT.**

1a) According to the label, what is this product used for?

DO NOT READ LIST. MULTIPLE RESPONSES ALLOWED.

Correct	EMERGENCY TREATMENT OF OPIOID OVERDOSE	1
Correct	EMERGENCY TREATMENT OF OVERDOSE	2
Correct	TO "REVIVE" SOMEONE DURING AN OVERDOSE FROM MANY PRESCRIPTION PAIN MEDICATIONS OR STREET DRUGS SUCH AS HEROIN	3
Correct	OPIOID OVERDOSE	4
Correct	HEROIN OVERDOSE	5
Correct	OVERDOSE OF PRESCRIPTION PAIN MEDICATIONS	6
Acceptable	DRUG OVERDOSE	7
Acceptable	OVERDOSE	8
<i>Incorrect</i>	DON'T KNOW	9
	OTHER (SPECIFY)	10

1b) Why do you say that?

1c) Can you tell me more about that?

Please turn to Card B. **READ CARD ALOUD TO THE PARTICIPANT.**

2a) According to the label, if you suspect an overdose, what will the person look like or be doing?

DO NOT READ LIST.

Correct	WILL NOT WAKE UP, IS VERY SLEEPY OR NOT BREATHING WELL	1
Correct	WILL NOT WAKE UP	2
Correct	VERY SLEEPY	3
Acceptable	NOT BREATHING WELL (E.G. BREATHING SLOWLY, SHALLOW, ETC.)	4
Correct	CAN'T AROUSE THE PERSON (OR OTHER SIMILAR RESPONSES)	5
<i>Incorrect</i>	DON'T KNOW	6
<i>Incorrect</i>	NOTHING	7
	OTHER (SPECIFY)	8

2b) Why do you say that?

The next few questions describe possible situations or scenarios that could occur to someone in real life. Also, please assume that each question has all the information you need in order to make a decision. Please do not try to guess the answers to the questions – either refer back to the labeling for this product or simply say you don’t know.

Please turn to Card C. **READ CARD ALOUD TO THE PARTICIPANT.**

IF PARTICIPANT DID NOT MENTION “CALL 911” DURING COGNITIVE WALKTHROUGH, READ:

- Dre’s cousin is overdosing on a prescription pain medicine.
- Dre just gave him a second dose of this medicine [POINT TO DFL] and he still is not waking up.

OR

IF PARTICIPANT MENTIONED “CALL 911” DURING COGNITIVE WALKTHROUGH, READ:

- Dre’s cousin is overdosing on a prescription pain medicine.
- Dre called 911 and just gave him a second dose of this medicine (POINT TO DFL).
- He still is not waking up.

3a) What, if anything, does the label say Dre should do now?

ROTATE ORDER OF THIS QUESTION AND Q.5A/B.

DO NOT READ LIST.

Correct	GIVE ANOTHER DOSE EVERY 2-3 MINUTES UNTIL THE PERSON WAKES UP	1
Correct	CONTINUE TO GIVE DOSES UNTIL THE PERSON WAKES UP	2
Acceptable	GIVE ANOTHER DOSE	3
Acceptable	CALL 911	4
<i>Incorrect</i>	STAY WITH THE PERSON UNTIL THE AMBULANCE ARRIVES	5
<i>Incorrect</i>	DON’T KNOW	6
<i>Incorrect</i>	NOTHING	7

	OTHER (SPECIFY)	8
--	-----------------	---

3b) Why do you say that?

Please turn to Card D. **READ CARD ALOUD TO THE PARTICIPANT.**

- Rodney’s friend is overdosing on a prescription pain medicine.
- Rodney gave his friend a dose of this medicine [POINT TO DFL], and his friend woke up but is sweating and feeling angry.

4a) What, if anything, does the label say about this?

DO NOT READ LIST.

Correct	SOME PEOPLE MAY EXPERIENCE SYMPTOMS WHEN THEY WAKE UP, SUCH AS SHAKING, SWEATING, NAUSEA, OR FEELING ANGRY	1
Correct	SOME PEOPLE MAY EXPERIENCE SYMPTOMS WHEN THEY WAKE UP	2
Correct	<ul style="list-style-type: none"> • RESPONSES SIMILAR TO: THE DRUG IS MAKING THEM FEEL THIS WAY AND IT SAYS SO ON THE LABEL OR • THIS IS TO BE EXPECTED OR • IT SOUNDS LIKE IT IS A NORMAL REACTION – IT SAYS SO ON THE LABEL OR • IT’S A REACTION TO THE DRUG THAT IS STATED ON THE LABEL 	3
Acceptable	I TOOK AWAY THEIR HIGH, OF COURSE THEY’RE GOING TO BE MAD	4
<i>Incorrect</i>	DON’T KNOW	5
<i>Incorrect</i>	NOTHING	6
	OTHER (SPECIFY)	7

4b) Why do you say that?

Please turn to Card E. **READ CARD ALOUD TO THE PARTICIPANT.**

IF PARTICIPANT DID NOT MENTION “CALL 911” DURING COGNITIVE WALKTHROUGH, READ:

- **Macy’s friend is overdosing on heroin**
- **Macy gave her friend 2 doses of this medicine (POINT TO DFL), and he is starting to wake-up.**

OR

IF PARTICIPANT MENTIONED “CALL 911” DURING COGNITIVE WALKTHROUGH, READ:

- **Macy’s friend is overdosing on heroin**
- **Macy called 911 and gave her friend 2 doses of this medicine (POINT TO DFL)**
- **He is now starting to wake-up.**

5a) What, if anything, does the label say Macy should do now?

ROTATE ORDER OF THIS QUESTION AND Q.3A/B.

DO NOT READ LIST.

Correct	STAY WITH THE PERSON UNTIL THE AMBULANCE ARRIVES	1
Acceptable	STAY WITH THE PERSON	2
<i>Incorrect</i>	DON'T KNOW	3
<i>Incorrect</i>	NOTHING	4
	OTHER (SPECIFY)	5

5b) Why do you say that?



Please turn to Card F. **READ CARD ALOUD TO THE PARTICIPANT.**

6a) According to the label, is it safe to keep giving doses of this medicine?

DO NOT READ LIST.

Correct	YES	1
<i>Incorrect</i>	NO	2
<i>Incorrect</i>	DON'T KNOW	3
	OTHER (SPECIFY)	4

6b) Why do you say that?

Please turn to Card G. **READ CARD ALOUD TO THE PARTICIPANT.**

- **Tiana’s friend is overdosing on heroin.**
- **Tiana gave her friend one dose of this medicine (POINT TO DFL) and called 911.**
- **Her friend woke up, but is now very sleepy again.**

7a) What, if anything, does the label say Tiana should do now?

DO NOT READ LIST.

Correct	GIVE ANOTHER DOSE IF THE PERSON BECOMES VERY SLEEPY AGAIN	1
Correct	GIVE ANOTHER DOSE	2
<i>Incorrect</i>	DON'T KNOW	3
<i>Incorrect</i>	NOTHING	4
	OTHER (SPECIFY)	5

7b) Why do you say that?

8a) What do you think the word “opioid” means?

DO NOT READ LIST.

Correct	PRESCRIPTION PAIN MEDICATIONS OR STREET DRUGS SUCH AS HEROIN	1
Acceptable	PRESCRIPTION PAIN MEDICATIONS	2
Acceptable	STREET DRUGS SUCH AS HEROIN	3
Acceptable	HEROIN	4
<i>Incorrect</i>	OPIUM	5
<i>Incorrect</i>	DON'T KNOW	6
<i>Incorrect</i>	NOTHING	7
	OTHER (SPECIFY)	8

9. Overall, would you say you had any trouble finding information on the label or following what to do or any confusion with the words or pictures?

- | | |
|--|---|
| <input type="checkbox"/> Identification issue (locating information) | <input type="checkbox"/> Navigation Issues (flow of words/concepts) |
| <input type="checkbox"/> Confusion with words | <input type="checkbox"/> Confusion with pictures |
| <input type="checkbox"/> None of the above | <input type="checkbox"/> Other |

10. Had you heard of naloxone before today?

	YES	1
	NO	2
	DON'T KNOW	3

11. Have you or someone you know ever used naloxone on someone?

	YES	1
	NO	2
	DON'T KNOW	3

Those are all of my questions. Thank you so much for your time.

TO THE BEST OF MY ABILITY AND KNOWLEDGE, THE INFORMATION ENTERED INTO THE SURVEY IS COMPLETE AND CORRECT, AND THE SURVEY WAS CONDUCTED ACCORDING TO THE METHODOLOGY I WAS INSTRUCTED TO FOLLOW, ACCORDING TO THE STUDY PROTOCOL.

INTERVIEWER PRINT NAME: _____

INTERVIEWER SIGN NAME: _____

ADULT REALM WORD LIST

List 1	List 2	List 3
fat	fatigue	allergic
flu	pelvic	menstrual
pill	jaundice	testicle
dose	infection	colitis
eye	exercise	emergency
stress	behavior	medication
smear	prescription	occupation
nerves	notify	sexually
germs	gallbladder	alcoholism
meals	calories	irritation
disease	depression	constipation
cancer	miscarriage	gonorrhea
caffeine	pregnancy	inflammatory
attack	arthritis	diabetes
kidney	nutrition	hepatitis
hormones	menopause	antibiotics
herpes	appendix	diagnosis
seizure	abnormal	potassium
bowel	syphilis	anemia
asthma	hemorrhoids	obesity
rectal	nausea	osteoporosis
incest	directed	impetigo

CONFER – TASK 3

#16020

SHOWCARDS

Card A

According to the label, what is this product used for?

Card B

According to the label, if you suspect an overdose, what will the person look like or be doing?

Card C-1

- Dre's cousin is overdosing on a prescription pain medication.
- Dre just gave him a second dose of this medicine and he still is not waking up.

What, if anything, does the label say Dre should do now?

Card C-2

- Dre's cousin is overdosing on a prescription pain medication.
- Dre called 911 and just gave him a second dose of this medicine.
- He still is not waking up.

What, if anything, does the label say Dre should do now?

Card D

- **Rodney's friend is overdosing on a prescription pain medication.**
- **Rodney gave his friend a dose of this medicine, and his friend woke up but is sweating and feeling angry.**

What, if anything, does the label say about this?

Card E-1

- **Macy's friend is overdosing on heroin.**
- **Macy gave her friend 2 doses of this medicine, and he is starting to wake-up.**

What, if anything, does the label say Macy should do now?

Card E-2

- **Macy's friend is overdosing on heroin.**
- **Macy called 911 and gave her friend 2 doses of this medicine.**
- **He is starting to wake-up.**

What, if anything, does the label say Macy should do now?

Card F

According to the label, is it safe to keep giving doses of this medicine?

Card G

- **Tiana's friend is overdosing on heroin.**
- **Tiana gave her friend one dose of this medicine and called 911.**
- **Her friend woke up, but is now very sleepy again.**

What, if anything, does the label say Tiana should do now?